

Trusted Research Environment Data Access Agreement Template

Scope:

This Agreement is intended for use where data is accessed within a Trusted Research Environment (TRE) for the purposes of research and development for the public good.

Between:

- (1) [Host Organisation name] whose registered address is [address] (the **Host Organisation**) and
- (2) [User Organisation name] whose registered address is [address] (the **User Organisation**)
(each '**Party**' and together '**Parties**')

Where data access will occur within the following TRE: [name] (the TRE)

The Host Organisation authorises access to Data in the TRE for Approved Researcher(s) from the User Organisation who have accepted the Terms of Use [Annex 1]. Access is authorised for the purposes of the Approved Project(s) [Annex 2] or Approved Purposes defined in Annex only:


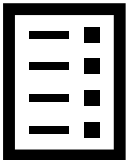
Project Details	
Approved Project(s)	[name/details of Approved Project(s)] as further defined in Annex 2 or Approved Purposes defined in Annex 3
Research Project Sponsor	[name of Sponsor (if applicable)]
Lead Researcher/Principal Investigator/ Main Applicant]	[name]
User Organisation	[name]
Term	[authorised duration of Approved Project(s)/Purposes]
Data	[description of datasets requested for Approved Project(s)/Purposes] as further defined in Annex 4

Responsibility:

The User Organisation is responsible for compliance by Approved Researchers with the terms of this Agreement and the Terms of Use [Annex 1] as further specified below.

Approved Researchers are not required to sign this Agreement but must accept the Terms of Use before accessing the TRE.

The terms below (including those set out in the **Annexes**) govern the access to the Data:

<p>1. Safe People</p> 	<p>1.</p> <p>1.1. The User Organisation shall:</p> <p>1.1.1. make Approved Researcher(s) aware of, and ensure Approved Researcher(s) comply with, the terms of this Agreement and the Terms of Use, and any breach by an Approved Researcher of the Terms of Use or this Agreement shall be a breach of the User Organisation of this Agreement;</p> <p>1.1.2. notify the Host Organisation within 5 working days of changes to Approved Researcher(s), including where an Approved Researcher has left the User Organisation or is no longer authorised to work on the Approved Project(s); and</p> <p>1.1.3. ensure that Approved Researchers do not share login details or access credentials to the TRE with any other person and do not attempt to access the Data or the TRE after they have been notified that they are no longer authorised to do so.</p> <p>1.2. The User Organisation warrants that the Approved Researcher(s) are appropriately trained and skilled in data protection, confidentiality, governance, and security, and to the standard specified in Annex</p> <p>1.3. The Host Organisation shall:</p> <p>1.3.1. terminate access to the Data on termination or expiry of the Agreement;</p> <p>1.3.2. following notification in accordance with clause 1.1.2 above, terminate access to the TRE for the relevant Approved Researchers; and</p> <p>1.3.3. in the event of a breach or suspected breach of this Agreement, including the Terms of Use, immediately suspend access to the Data for one or more Approved Researcher(s) and fully investigate the breach or suspected breach and may apply further penalties and/or require remediations as set out in Annex 6.</p> <p>1.4. If there is any conflict between the Terms of Use and this Agreement, this Agreement shall prevail.</p>
<p>2. Safe Projects</p> 	<p>2.</p> <p>2.1. The User Organisation shall access and use the Data in the TRE:</p> <p>2.1.1. in accordance with Applicable Laws;</p> <p>2.1.2. for the Approved Project(s) only, in line with the approved project scope for research in the public good [as defined in Annex 2], or where access is permitted under this Agreement for other Approved Purposes [Annex 3], and not for any other purposes ; and</p> <p>2.1.3. in accordance with all applicable ethical standards and approvals.</p> <p>2.2. The Host Organisation shall publish accurate and up to date details of the Approved Project(s) and associated Approved Researcher(s) in a publicly available data use register.</p> <p>2.3. The Approved Project(s) may only be varied by following the procedure set out in Annex 7.</p>

3. Safe Settings




- 3.
- 3.1. The Host Organisation shall ensure that the TRE and processing arrangements implement appropriate technical and organisational measures in compliance with Data Protection Laws.
- 3.2. The User Organisation shall ensure that the Approved Researchers:
 - 3.2.1. keep the Data and any access credentials to the Data confidential in accordance with Applicable Laws and with at least the same degree of care used to protect its own confidential information;
 - 3.2.2. do not access, use, or disclose the Data other than as permitted by this Agreement or as required by Applicable Laws; and
 - 3.2.3. do not introduce or permit the introduction of any virus, software, code, file or programme into the TRE which could compromise its security, or the security of the Data, and shall ensure that the End User security requirements set out in **Annex 8** are followed by the Approved Researcher(s).
- 3.3. The Host Organisation shall monitor and audit the use of the TRE and the Data by the User Organisation and its Approved Researcher(s) to ensure compliance with the terms of this Agreement in accordance with the protocol set out in **Annex 9**.

4. Safe Data



- 4.
- 4.1. The User Organisation shall ensure that the Approved Researchers do not, and do not attempt to:
 - 4.1.1. identify individuals from the Data;
 - 4.1.2. contact any Research Participant; or
 - 4.1.3. link or combine the Data with other information or data (including any information relating to an identified or identifiable natural person) available to the User Organisation without permission from the Host Organisation.
- 4.2. The User Organisation acknowledges and agrees that it has sole responsibility, and the Host Organisation takes no responsibility, for interpretation or further analysis of the Data.
- 4.3. The User Organisation will inform the Host Organisation without delay, and in any event within 12 hours of becoming aware of:
 - 4.3.1. any unauthorised access, disclosure, loss damage or alteration of the Data;
 - 4.3.2. any element within the Data that might permit the identification of a Research Participant;
 - 4.3.3. any event which may impact the confidentiality, integrity or availability of the Data including cyber security incidents;
 - 4.3.4. any complaints in relation to the Data including complaints from an individual or supervisory authority; and
 - 4.3.5. any request from a Research Participant to exercise their rights in respect of the Data.
- 4.4. To the extent required by Data Protection Laws, the Host Organisation shall notify data protection supervisory authorities and – where applicable – notify affected data subjects in the event

	<p>of a personal data breach (provided that the User Organisation shall not be restricted from making such notifications in cases where such notifications are required by Data Protection Legislation and the Host Organisation fails to make such notifications in accordance with the requirements of Data Protection Legislation). The parties will collaborate in this regard as appropriate.</p> <p>4.5. Host Organisation shall be responsible for responding to data subject rights requests submitted to either party in an appropriate and legal manner. User Organisation shall provide reasonable assistance to Host Organisation where this is necessary in order to respond.</p> <p>4.6. Where the Approved Project(s) involve access to linked NHS data, the provisions in Annex 16 shall apply.</p>
<p>5. Safe Outputs</p> 	<p>5.</p> <p>5.1. The User Organisation may only publish, distribute or otherwise share Research Outputs that have been approved in accordance with the process set out at Annex 10 and the Output acknowledgment policy set out in Annex 11. Research Outputs must not include Personal Data.</p> <p>5.2. The User Organisation shall not:</p> <p>5.2.1. use any Research Output for any purpose contrary to Applicable Laws or Approved Project(s) purposes; or</p> <p>5.2.2. download, extract, transmit, transfer, remove, share, copy, or publish any of the Data from the TRE (but this shall not prevent the publication of Research Outputs in accordance with Annex 11).</p>
<p>6. Intellectual Property</p>	<p>6.</p> <p>6.1. This Agreement is not intended to constitute any transfer of Intellectual Property Rights in the Data or the TRE.</p> <p>6.2. Ownership of Intellectual Property Rights is set out in Annex 13.</p> <p>6.3. Unless otherwise specified in Annex 13, Intellectual Property Rights in the Research Outputs shall belong to the User Organisation.</p>
<p>7. Research uncertainty/ no warranty</p>	<p>7.</p> <p>7.1. It is generally not possible to know with certainty at the outset of research whether access to and use of particular datasets will answer the relevant research question or produce valuable outputs, therefore to the fullest extent permitted under Applicable Laws, the Host Organisation:</p> <p>7.1.1. makes no warranty, express or implied as to the quality of the Data or its suitability for the Approved Project(s); and</p> <p>7.1.2. excludes all liability for actions, claims, proceedings, demands, losses, costs, awards, damages, and payments suffered or made by the User Organisation that may arise from their use of the Data or unavailability of the Data for whatever reason.</p> <p>7.2. The liability provisions in Annex 19 apply.</p>

<p>8. Compliance with Laws</p>	<p>8.</p> <p>8.1. Each Party shall comply with their respective obligations under all Applicable Laws, including Data Protection Laws.</p> <p>8.2. If the User Organisation is outside the UK and not in a country in respect of which an adequacy decision under Art.45 UK GDPR applies¹, the terms at Annex 17 will apply.</p> <p>8.3. If either Party is obliged to respond to requests under the Freedom of Information Act 2000 ('FOIA'²), and a request is received regarding the Data, the other Party shall provide reasonable assistance to the Party in receipt of the request to comply with its obligations under FOIA. The Party subject to any request under FOIA retains overall discretion for responding to requests made under FOIA.</p>
<p>9. Cost Recovery and Service Levels</p>	<p>9. The Host Organisation may charge fees for providing the User Organisation with access to the TRE in accordance with the Cost Recovery Policy set out in Annex 14.</p> <p>10. Applicable service levels and helpdesk support facilities provided by the Host Organisation are set out in Annex 18</p>
<p>10. Further provisions</p>	<p>11.</p> <p>11.1. This Agreement is drafted in the English language. If this Agreement is translated into any other language, the English language version shall prevail. All other documents provided under or in connection with this Agreement shall be in English or accompanied by a certified English translation.</p> <p>11.2. This Agreement constitutes the entire agreement between the Parties. No variation of this Agreement shall be effective unless it is agreed in writing and signed by the Parties or their authorised representatives.</p> <p>11.3. Any notices under this Agreement shall be in writing sent to the Parties registered address or by email: for Host Organisation: [insert email address]; and for the User Organisation [insert email address].</p> <p>11.4. No person other than a Party to this Agreement shall have any rights to enforce any term of this Agreement.</p> <p>11.5. Either Party may terminate this agreement by thirty (30) days' written notice to the other Party.</p> <p>11.6. The Term of this Agreement is set out in Annex 7 and may be extended by following the procedure set out in Annex 7.</p> <p>11.7. This Agreement, its subject matter, or its formation (including non-contractual disputes or claims) shall be governed and construed in accordance with the laws of England and Wales and the Parties agree to the exclusive jurisdiction of the English Courts (including non-contractual disputes or claims).</p>

¹ **Note:** these are: countries in the EEA, as well as Andorra, Argentina, Canada (commercial organisations), Gibraltar, Guernsey, Isle of Man, Israel, Japan (private sector), Jersey, New Zealand, Republic of South Korea, Switzerland and Uruguay.

² **Drafting note:** if the governing law in clause 9 below is Scottish law, please update this reference to include "Freedom of Information (Scotland) Act 2002 ('FOISA')" and update the rest of this clause accordingly.

Signatories:

Signed by an authorised representative for and on behalf of the User Organisation:	
Signed by an authorised representative for and on behalf of Host Organisation:	

The following definitions apply in the Agreement:

“Agreement” means this Trusted Research Environment (TRE) Data Access Agreement including the Annexes hereto and the Terms of Use.

“Applicable Laws” means all applicable laws, statutes, regulations, and codes from time to time in force including Data Protection Laws.

“Approved Project(s)” means the project(s) identified in **Annex 2** below.

“Approved Purposes” means the purposes identified in **Annex 3** below.

“Approved Researcher(s)” means Researcher(s) whose access to and use of the Data in the TRE for the Approved Project(s) or Approved Purposes has been approved in writing by the Host Organisation to the User Organisation, and who have entered the Terms of Use, prior to such access or use, and such approval has not been revoked by the Host Organisation.

“Data” means the data fields and datasets to which the User Organisation has been approved access as described above.

“Data Protection Laws” means any Applicable Laws with respect to data protection and privacy, including the General Data Protection Regulation ((EU) 2016/679) (“GDPR”), the UK GDPR (as defined in the UK Data Protection Act 2018) and/or Data Protection Act 2018, as applicable to either Party and or the activities under this Agreement.

“Host Organisation” means the organisation which is accredited to host and control the TRE.

“Intellectual Property Rights” means the patents, rights to inventions, copyright and related rights, moral rights, trademarks and service marks, business names and domain names, rights in get-up, goodwill and the right to sue for passing off, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets) and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

“Personal Data” has the meaning given to it in Data Protection Laws.

“Principal Investigator” means the individual specified above.

“Research Output” means any data, learning, discovery, insight, paper, publication, or other results arising out of an Approved Project.

“Research Participant” means an individual whose data forms part of the Data.

“Term” means the duration of the Agreement as provided above.

“Terms of Use” means the Terms of Use of the TRE which will be accepted individually by Approved Researchers as users of the TRE.

“User Organisation” means the organisation which is responsible for individuals using a TRE service.

“Working Day” means any day other than a Saturday, Sunday, or public holiday in the UK country in which the Host Organisation is based.

Annexes

The Annexes are customisable to the individual requirements for the TRE. Host Organisations shall follow the guidance for each Annex when deciding on what information to include. Duplication between the terms above and the Annexes should be avoided and where there is conflict with any terms in the annexes and the main Agreement, the terms of the main Agreement shall prevail.

Annex 1

Terms of Use

Guidance: Annex 1 contains Terms of Use that may be used for approved researcher access to a TRE. It is recommended that the Terms of Use present as ‘click through’ terms that the Approved Researchers accept when accessing the TRE. If there are Terms of Use already in place for the TRE, insert them here and the below terms will not apply.

Terms of Use:

The Approved Researcher agrees that they must:

1. Complete the Office for National Statistics (ONS) Safe Researcher Training prior to accessing the TRE/SDE (or equivalent as defined in **Annex 5** of the Data Access Agreement)
2. Adhere to all relevant data protection legislation, including the UK General Data Protection Regulation (GDPR) and the UK Data Protection Act (2018).
3. Always preserve the confidentiality of the Data.
4. Use the data for research for public good and only within the Approved Project scope and purposes (as defined in **Annex 2** of the Data Access Agreement).
5. Notify the Host Organisation immediately of any breach of data in the TRE or incident that may have compromised the security of the Data.
6. Ensure that they are not overlooked by unauthorised persons when accessing the TRE.

The Approved Researcher agrees that they must not:

7. Share access credentials or give access to Data in the TRE to any other person.
8. Leave their device unattended while accessing the TRE.
9. Link data to any other dataset other than those defined in the Approved Project.
10. Attempt to copy or remove Data or analyses of the Data from the TRE without following the TRE Output Checking Policy as defined in **Annex 10** of the Data Access Agreement.
11. Attempt to identify or contact any individual using Data in the TRE.

I agree that I have fully read and understood the Data Access Agreement and the Terms of Use above: [Approved Researcher enters their name and User Organisation name as acknowledgement]

Annex 2

Approved Project(s) Description

Guidance: Annex 2 can cover a single project or multiple projects. Annex 2 can include the following:

- A detailed summary of the project objectives and statistical analysis plan
- Attach the approved application form(s)
- Reference to separate approval system where the Approved Project(s) scope is clearly set out.

Annex 3

Other approved purposes for TRE access

Guidance: Access to the data may be permitted for a purpose other than a research study such as access for testing, audit, or feasibility counts. Where applicable, Annex 3 should set out terms related to access for such purposes.

Annex 4

Datasets/Data fields available

Guidance: The purpose of this section is to detail the datasets available for analysis and (if applicable) linkage in the TRE.

Annex 5

Approved Researcher training requirements

Guidance: Details of the training or accreditation requirements prior to requesting Approved Researcher status to access data in the TRE as part of an Approved Project. For example, this section could state that Researchers should undertake the Office for National Statistics (ONS) Safe Researcher Training (SRT) and achieve full accreditation status, or provisional accreditation where access to the TRE will be under supervision of an Approved Researcher with full accreditation status. Where a TRE will not use the ONS SRT accreditation, an equivalent standard of training must be demonstrated, and will be detailed here:

Annex 6

Non-compliance, Offences and Penalties

Guidance: Penalties and remediation required for breaches of this Agreement, including self-reported breaches, as defined by the Host Organisation should be described here:

Annex 7

Term and Conditions of extension/amendment submission

Guidance: Set out:

- The agreed Term for data access, and whether this is for the duration of the project or a defined period (for example, 12 months).

- The process for submitting a request for an extension to the Term of the Approved Project(s)
- The process for submitting amendments to the scope or purposes (whether commercial or non-commercial) of the Approved Project(s).

Annex 8

End user security requirements

Guidance: The User Organisation is responsible for ensuring that electronic devices used to access the TRE are fit for purpose and are secured through the implementation of access control mechanisms. Further end user security requirements defined by the Host Organisation should be listed in this section, along with the means of checking these (this may be part of the application for an Approved Project process):

Annex 9

TRE protocol on monitoring use/audit/compliance

Guidance: The Host Organisation protocol for monitoring access to and use of the TRE should be inserted here. It is recommended that the protocol is made publicly available and accessible via the Host Organisation website.

Annex 10

TRE output checking policy

Guidance: This purpose of this section is to define the process the TRE will have in place for checking/auditing the anonymous outputs prior to release, and detail disclosure control. It is recommended that the policy is made publicly available and accessible via the Host Organisation website.

Annex 11

Output acknowledgement/Publications policy

Guidance: Requirements for inclusion of acknowledgements in any outputs from the TRE using data (including any Data under licence) should be defined here. It is recommended that the policy is made publicly available and accessible via the Host Organisation website.

Annex 12

Open sharing of code, syntax, or methodology

Guidance: Sharing of code, syntax, and methodology, where possible, is encouraged to avoid duplication of efforts amongst the research community. Sharing should occur through the channels specified here, and ownership detailed. It is recommended that the policy is made publicly available and accessible via the Host Organisation website.

Annex 13

Intellectual property rights

Guidance: Ownership of Intellectual Property Rights relating to source data, linked data, derived data, metadata, researcher analyses and Research Outputs may be specified in detail here:

The following example is for reference:

[Intellectual Property Policy - Grant Funding | Wellcome](#)

[Consent and revenue and equity sharing policy - Grant Funding | Wellcome](#)

Annex 14

Cost recovery policy

Guidance: The Host Organisation policy for pricing and/or recovering costs associated with accessing data in the TRE should be inserted here:

The following example is for reference:

[Pricing | CPRD](#)

Annex 15

Conditions of permitted linkage

Guidance: Approved Researchers may not attempt to match or link the Data to any other data from any other source without express permission. Conditions relating to the linkage of datasets held within the TRE and any permitted datasets that may be ingested into the TRE (if applicable) are defined here:

Annex 16

Additional terms for sublicensed data

Guidance: Where the User Organisation is accessing sublicensed linked Data (for example, Hospital Episode Statistics from NHS England), the following additional conditions will apply:

Annex 17

International Data Transfer Agreement

Guidance: [TBC]

Annex 18

Service Levels

Guidance: Set out details of agreed availability times and support services provided by the Host Organisation. This Annex can be left blank where not applicable.

Example text:

Availability

The Host Organisation shall use reasonable endeavours to provide access to the Data within the TRE to the Approved Researchers [through its website] from [time - time] on [working days] throughout the Term.

The Host Organisation may effect maintenance, repairs or updates to the TRE and the Data and wherever reasonably practicable shall give the Approved Researchers twenty-four (24) hours' notice of any interruption of access to the Data by email. In case of urgent maintenance or repairs, the TRE may be unavailable without notice.

Technical Support

The Host Organisation will provide technical support to the Approved Researchers from [time-time] on [working days] throughout the Term.

The Approved Researcher will use reasonable endeavours to provide the Host Organisation with sufficient information required to answer any query submitted. The Host Organisation will use reasonable endeavours to respond to the Approved Researcher's queries within [specified response time] and if the Host Organisation reasonably considers that the Approved Researcher is making excessive use of technical support, the Host Organisation at its sole discretion may charge the User Organisation a service fee for any further queries submitted.

Annex 19

Liability

Guidance: Set out details of liability (or no liability) between the parties for actions, claims, proceedings, demands, losses, costs, awards, damages, and payments by either party that may arise from breach of this Agreement (other than use of the data or unavailability for which liability is already excluded under clause 7). Include liability caps/limits where applicable. Specify whether any indirect or consequential loss or damage, loss of profit or loss or contracts, loss of business opportunity, revenue, goodwill or anticipated savings are recoverable.

Include indemnity if applicable.